



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,164	08/30/2006	Naoki Nagahara	2006_1328A	6045
513	7590	11/21/2008	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P.			DICKINSON, PAUL, W	
2033 K STREET N. W.			ART UNIT	PAPER NUMBER
SUITE 800			1618	
WASHINGTON, DC 20006-1021			MAIL DATE	DELIVERY MODE
			11/21/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,164	<b>Applicant(s)</b> NAGAHARA ET AL.
	<b>Examiner</b> PAUL DICKINSON	<b>Art Unit</b> 1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 August 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 3,6,13 and 14 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,4,5,7-12 and 15-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/24/2008
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant's arguments, filed 8/7/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Response to Arguments******Claim Rejections - 35 USC § 102/103***

The rejection of Claims 1-2, 7-12, and 15 under 35 U.S.C. 102(e) as being anticipated by US 20050181052 ('052) is maintained. The rejection of Claims 4 and 16-24 under 35 U.S.C. 103(a) as being unpatentable over US 20050181052 ('052) is maintained. The rejection of Claim 5 under 35 U.S.C. 103(a) as being unpatentable over US 20050181052 ('052) in view of US 5665348 ('348) is maintained.

Applicant argues that '052 is limited to a gelatin capsule and the Examples disclose only a hard gelatin capsule. Such a hard gelatin capsule, or a HPMC capsule which has as problem that solubility is low at low pH is excluded from the present invention. Instant Claim 1-6 refer to the capsule itself, and not to the contents of the capsule.

Applicant's arguments have been fully considered but are not found persuasive. The features upon which applicant relies are not recited in the rejected claims. Although the claims are interpreted in light of the specification,

Art Unit: 1618

limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). There is no requirement in the claims that hard gelatin capsules are excluded from the invention. It should be noted that in the disclosure of '052, hard gelatin capsules are only one preferred and non-limiting embodiment of the invention (see paragraph 63). For the reasons set forth in the previous office action, the capsule preparation disclosed by '052 is stable in a low moisture state and has pH-independent disintegration properties. The capsule preparation disclosed by '052 thus meets every limitation of the instant claims. Regarding the exclusivity of the term "capsule" as recited in Claims 1-6 to refer to the capsule (i.e. the capsule shell), and not the contents, the Examiner must give the claims their broadest reasonable interpretation. There is no limiting definition of "capsule" provided in the specification, and a capsule as recited in Claims 1-6 reasonably encompasses the entire capsule, including the capsule shell and contents, not the capsule shell only. Thus, in the broadest reasonable interpretation, both the capsule shell and the capsule contents together constitute the capsule.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number

Art Unit: 1618

is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson  
Examiner  
AU 1618

November 18, 2008